

Message Text

PAGE 01 STATE 138793
ORIGIN HEW-06

INFO OCT-01 ISO-00 OES-07 AF-10 ARA-14 EA-12 EUR-12
NEA-11 MED-03 IO-14 /090 R

DRAFTED BY DHEW/FDA: JRWEINROTH, MD:VO
APPROVED BY OES/ENP/EN: BLONG
DHEW/PHS/OASH/OIH: MKEFAUVER
ARA/ECA:JBUMPUS(INFO)
EUR/CE:JHURLEY,JR(INFO)
EA/ANP:TWAJDA(INFO)
EUR/NE:WNEWLIN(INFO)
EUR/NE:CSCHALLER(INFO)
EUR/WE:JDOBBINS(INFO)
EUR/CE:SKLINGAMAN(INFO)
EUR/NE:SWORREL(INFO)
EA/J:EFEATHERSTONE(INFO)
EUR/NE:DDONCHI(INFO)
AF/S:JTAYLOR(INFO)
EUR/WE:AHUGHES(INFO)
EUR/NE:RWOODS(INFO)
EA/ROC:WLUNDY

-----039983 012233Z /70

P 011949Z JUN 78
FM SECSTATE WASHDC
TO AMEMBASSY BUENOS AIRES PRIORITY
AMEMBASSY VIENNA PRIORITY
AMEMBASSY CANBERRA PRIORITY
AMEMBASSY BRUSSELS PRIORITY
AMCONSUL SAO PAULO PRIORITY
AMCONSUL RIO DE JANEIRO PRIORITY
AMEMBASSY COPENHAGEN PRIORITY
AMEMBASSY PARIS PRIORITY
AMEMBASSY BONN PRIORITY
AMEMBASSY LONDON PRIORITY
AMEMBASSY TOKYO PRIORITY
AMEMBASSY THE HAGUE PRIORITY
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AMEMBASSY OSLO PRIORITY
AMEMBASSY PRETORIA PRIORITY
AMEMBASSY MADRID PRIORITY
AMEMBASSY STOCKHOLM PRIORITY
AMEMBASSY BERN PRIORITY
AMEMBASSY TAIPEI PRIORITY
INFO AMEMBASSY BRASILIA PRIORITY

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E.O. 11652:N/A

TAGS: OGEN, ETRD, EIND, TBIO, AR, AU, AS, BE, BR, DA, FR,

SUBJECT:FDA ADVISORY - DEFECTIVE INTRA-AORTIC BALLOON
PUMPS (RECALL T-098-8)

1. FDA ADVISES OF THE FOLLOWING:

PRODUCT INVOLVED AND IDENTIFICATION - (A) AVCO INTRA-AORTIC
BALLOON PUMP, MODEL 10 (IABP) A ELECTRONIC DEVICE FOR
PROFESSIONAL USE ONLY. IT OPERATES WITH THE PATIENT'S
ECG PERMITTING PROPER PUMPING WITH MOST CARDIAC RHYTHMS.
DESIGNED AS A CARDIAC ASSIST SYSTEM, USED BEFORE, DURING
AND AFTER HEART SURGERY. DISTRIBUTED AND SERVICED BY
ROCHE MEDICAL ELECTRONICS, INC., BRICK YARD ROAD,
CRANBURY, NEW JERSEY 08512. DEVICE ALSO SOLD AS ROCHE
MEDICAL ELECTRONIC'S MODEL 3010. (B) ALL SERIAL NUMBERS
ARE INVOLVED.

2. MANUFACTURER/RECALLING FIRM:

AVCO MEDICAL PRODUCTS
9 PLYMOUTH ST.
EVERETT, MA 02149
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3.DISTRIBUTOR: ROCHE MEDICAL ELECTRONICS, INC., CRANBURY,
NEW JERSEY 08512

4. REASON FOR RECALL:

FOLLOWING DEATH DURING SURGERY AS RESULT OF MALFUNCTION
OF INTRA-AORTIC BALLOON PUMP, THE FIRM ISSUED "RECALL"
BY TELEGRAM ON APRIL 2, 1978. THE CONTENT FIRM'S ADVISORY
READS ESSENTIALLY AS FOLLOWS:

5. URGENT - HOSPITAL ADMINISTRATOR

"IT HAS BEEN LEARNED THAT CERTAIN ELECTRONIC COMPONENTS
INCORPORATED IN AVCO'S MODEL 10 INTRA-AORTIC BALLOON
PUMP MAY BE COUNTERFEITS WHICH CAN CAUSE ECG TRIGGERING
MALFUNCTIONS OR OTHERWISE CAUSE THE MODEL 10 NOT TO
OPERATE AS INTENDED. IT IS NOT POSSIBLE FOR YOU TO
IDENTIFY THESE COUNTERFEIT COMPONENTS.

6. ACCORDINGLY, WE ARE NOTIFYING YOU THAT THE MODEL 10
SHOULD NOT BE USED EXCEPT WHERE ABSOLUTELY NO ALTERNATIVE
IS AVAILABLE. IN THOSE SITUATIONS WHERE THE MODEL 10
MUST BE USED, CONSTANT SURVEILLANCE OF THE UNIT MUST BE
MAINTAINED. IF YOU ENCOUNTER A DIFFICULTY WITH USE OF
THE MODEL 10, AVCO IS MAINTAINING A 24-HOUR TELEPHONE
NUMBER WHERE ASSISTANCE MAY BE OBTAINED: (COLLECT)
617-389-6400

7. WE ARE IMMEDIATELY IMPLEMENTING A PROGRAM OF IN-

HOSPITAL INVESTIGATION OF ALL MODEL 10'S IN ORDER TO IMPLEMENT APPROPRIATE CORRECTIVE ACTION. PLEASE DIRECT THIS NOTIFICATION IMMEDIATELY TO ALL PERSONNEL RESPONSIBLE FOR USE OF THE MODEL 10 IABP. CORRECTIVE ACTION CONSISTS OF REPLACING ALL READ OUT MEMORY CIRCUITS IN THE MINI COMPUTER OF THE IABP. "

8. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO UNCLASSIFIED

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DETERMINE IF THEY HAVE BEEN INFORMED OF PROBLEM AND CORRECTIVE ACTION REQUIRED. CONSIGNEES SHOULD ALSO BE ASKED IF RETROFIT PROGRAM IS CORRECTING THE PROBLEMS BEING EXPERIENCED WITH THIS PRODUCT.

9. FOREIGN CONSIGNEES AS FOLLOWS:
ARGENTINA -

DR. R.G. RAFOROLO, GUEMES CLINIC, XORDOB 3933, BUENOS AIRES

AUSTRIA

PR. H. HERGMANN, DOZENT BRUECKE, OBERARZT NECEK, KRACKENHAUS LINZ/DONAU, KRANKENHAUSTR. 9, LINZ

PR. KRAFT-KINZ, GRAZ

DR. KUBIENA, DOZENT ENENKEL, LAINZ

AUSTRALIA

DR. L. BERNSTEIN, ROYAL PRINCE ALFRED HOSPITAL, MISSENDON RD., CAMPERDOWN, SYDNEY

DR. J. CLAREBOROUGH, ST VINCENTS HOSPITAL, VICTORIA PDE, FITZROY, MELBOURNE

DR. G. CLARKE, ROYAL PERTH HOSPITAL, WELLINGTON ST, PERTH, WESTERN AUSTRALIA

DR. G.L. DONNELLY, ROYAL NORTH SHORE HOSPITAL, PACIFIC HIGHWAY, ST. LEONARDS, SYDNEY

DR. E. EIKENS, PRINCE HENRY HOSPITAL, ANZAC PDE, LITTLE BAY, SYDNEY

DR. R. LVOFF, ST. GEORGE HOSPITAL, BELGRAVE ST., KOGARAH, SYDNEY

DR. M. O'BRIEN, PRINCE CHARLES HOSPITAL, CHERMSIDE BRISBANE, QUD

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DR. M.F. O'ROURKE, ST VINCENTS HOSPITAL, VICTORIA ST., DARLINGHURST, SYDNEY

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DR. D. WALLACE - DR. E. ALFRED, ROYAL NEWCASTLE HOSPITAL,

NEWCASTLE, NSW

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HAUTE 322, 1000 BRUXELLES
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DE LA DUCHERE, 6060 GILLY
DR. BUISSET, INSITU MEDICO-CHIRURGICAL DE BRUXELLES,
SQUARE MARIE LOUISE 58, 1040 BRUXELLES

BRAZIL

DR. M. BARBERO MARCIAL, PRIMEIRA CLINICA CIRURGICA,
HOSPITAL DAS CLINICAS DA UNIVERSIDADE DE SAO PAULO,
SAO PAULO
DR. DOMINGOS JUNQUEIRA, HOSPITAL DA LAGOA 2A, CCT, RUA
JARDIM BOTANICO 501, RIO DE JANEIRO
DR. JOSE LUDOVICI, HOSPITAL ISRAELITA ALBERT EINSTEIN,
AV. ALBERT EINSTEIN 605/701, SAO PAULO
DR. W. RORTZ - DR. L. VAZ DE MELLO, HOSPITAL DOS SERVIFORES
DO ESTADO DO RIO DE JANEIRO, RUA SACADURA CABRAL 178,
RIO DE JANEIRO
DR. WALDOMIRO DE PAULA, PRONTO SOCCORO DO HOSPITAL DAS
CLINICAS DA FAC, MEDICINA DA USP, SAO PAULO
DR. E.J. ZERBINI, CIRURGICA CARDIO-VASCULAR, REAL E
BENNERITA SOX. PORTUGUESA DE BENEFICENCIA, SAO PAULO

DENMARK

M.D. J.H. RYGG - M.D. CARSTENSEN, UNIVERSITY HOSPITAL CPH,
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JAY, 51090 REIMS
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PR. BINET, MARIE LANNELONGUE, 129 RUE DE TOLBIAC, 75013
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PR. BOUDARIAS, HOSPITAL AMBROISE PARE, 9 AVENUE CHARLES DE
GAULLE, 92100 BOULOGNE BILLANCOURT
PR. BOUVRAIN, HOSPITAL LARIBOISIERE, 2 RUE AMBROISE PARE,
75475 PARIS
PR. CABROL - PR. GUIRAUDON, GROUPE HOSPITALIER PITIE-
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34059 MONTPELLIER

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11, 8000 MUNCHEN 19

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<< END OF DOCUMENT >>

Message Attributes

Automatic Decaptioning: X
Capture Date: 26 sep 1999
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
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Control Number: n/a
Copy: SINGLE
Draft Date: 01 jun 1978
Decaption Date: 01 jan 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 jan 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
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Drafter: DHEW/FDA: JRWEINROTH, MD:VO
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Executive Order: N/A
Errors: n/a
Expiration:
Film Number: D780230-0109
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
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Line Count: 401
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Litigation Codes:
Litigation History:
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Message ID: 8c2b4f7e-c288-dd11-92da-001cc4696bcc
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Review Withdrawn Fields: n/a
SAS ID: 2176290
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY - DEFECTIVE INTRA-AORTIC BALLOON PUMPS (RECALL T-098-8)
TAGS: OGEN, ETRD, EIND, TBIO, AR, AU, AS, BE, BR, DA, FR, FDA
To: BUENOS AIRES VIENNA MULTIPLE
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/8c2b4f7e-c288-dd11-92da-001cc4696bcc
Review Markings:
Sheryl P. Walter
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US Department of State
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